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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Outpatient Rehabilitative and Habilitative Services

Appropriate Use Criteria: Site of Care

Proprietary

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Table of Contents

Table of Contents	2
Description and Application of the Guidelines	3
General Clinical Guideline	4
Clinical Appropriateness Framework	4
Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions	4
Repeat Diagnostic Intervention	
Repeat Therapeutic Intervention	5
Site of Care for Outpatient Physical, Occupational, and Speech Therapies	6
General Information/Overview	
Clinical Indications	6
References	
Codes	
History	8

Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter "the Carelon Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines.

Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) be current enough to accurately reflect the clinical situation at the time of the requested service, and b) contain the elements necessary to determine compliance with guideline criteria without Carelon physician reviewers having to make assumptions or interpretations about an ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

• Repeated diagnostic testing at the same facility due to technical issues

- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. For situations wherein ongoing services might be appropriate, requests for subsequent services may be denied until completion of the previously authorized services so that patient response to the previously authorized services can be considered.

Site of Care for Outpatient Physical, Occupational, and Speech Therapies

General Information/Overview

Scope

These guidelines address site of care for outpatient physical (PT), occupational (OT), and speech therapies (ST). Specifically, the guidelines outline the medical necessity criteria for providing such services at a hospital outpatient department (HOPD) where a higher level of care and support may be available relative to a freestanding or independent clinic. In short, the provision of therapies within HOPD facilities can be considered appropriate when they offer equipment and/or level of support which are unavailable at non-HOPD sites and necessary to render outpatient therapy services safely and effectively when that request meets Carelon's clinical guidelines for appropriate use.* This guideline covers all requests for outpatient rehabilitation and habilitation therapies for all disciplines (PT, OT, ST) for both pediatric and adult patients.

See the <u>Code</u> section for a list of services included in these guidelines.

*Note: Not all procedures that are subject to Site of Service review also require medical necessity review of the procedure itself. Some may only be subject to Site of Care review.

Definitions

Hospital outpatient department (HOPD): Hospital-based department at which therapy services are rendered to outpatients

Non-hospital outpatient department (non-HOPD): Freestanding and/or off-campus therapy facility that is not operating as an HOPD

Clinical Indications

The following section includes indications for which outpatient physical, occupational, and speech therapies are considered medically necessary, along with supporting evidence where available.

Site of Care

Providing PT, OT, or ST at a hospital outpatient site of care (HOPD) is considered medically necessary for requests meeting criteria per Carelon's Outpatient Rehabilitation and Habilitation Therapies guidelines (or for services that don't require prior authorization themselves) when **ANY** of the following reasons exist:

- Specialized equipment is necessary to achieve the therapeutic goals, which requires **BOTH** of the following:
 - The specialized equipment is available only in the hospital-based facility (e.g., ceiling-mounted gait device that allows for variable weight-bearing, bariatric tables)
 - Therapeutic goals could not reasonably be achieved with use of alternative equipment that is more widely available
- Specialized therapy and/or assessments (e.g., for certain equipment) are necessary to achieve therapeutic goals, which requires **ANY** of the following:
 - Subspecialized therapist (e.g., pediatric speech therapist)
 - Collaborative and coordinated care between more than one discipline (e.g., co-treatment with PT and OT, or therapist and wound team)

- Clinical complexity requires access to higher level care, which requires **ANY** of the following:
 - Patient's underlying condition requires medical monitoring beyond the capabilities of the freestanding therapy facility
 - There is a potential need for immediate medical evaluation and care due to the patient's underlying condition and/or to the rendering of certain therapies (e.g., high risk of acute cardiac event, stroke, or seizures)
 - When performance of therapies outside the HOPD would reasonably be expected to create clinically significant delays in care
- Geographic inaccessibility* of freestanding clinics presents a barrier to timely and appropriate therapy
 *Note: The definition of "inaccessibility" may vary per individual health plan policy

Rationale

With the widespread expansion of freestanding therapy clinics, access to routine therapy services in communities has greatly increased beyond the HOPD. As a result, overall reliance on HOPDs for therapies is less, which are more appropriately reserved for those situations in which the capabilities of HOPD therapy can uniquely improve care. While there are no studies formally comparing the quality of rehabilitative/habilitative therapies delivered in the HOPD and freestanding environments, there are some differentiating characteristics between the two settings which generally bear on determination of the most appropriate setting for a given clinical scenario. On a high level, this would include considerations related to equipment, medical needs, specialized care, and access. The need to perform HOPD-based therapies is therefore based on principle-based patient, personnel, or technical factors that are expected to offer net benefit to HOPD-based therapies by making them safer and/or more effective than therapies in freestanding facilities when available.

HOPD may offer specialized equipment and expertise that is not widely available in freestanding facilities. While the exact capabilities vary from market to market, the vast majority of freestanding facilities offer physical therapy. Yet relatively few offer speech therapy, particularly pediatric speech therapy whose specialized practitioners typically practice only within a hospital (or school) setting. Similarly, HOPD therapy clinics are generally more likely to have advanced equipment (e.g., ceiling mounted gait-training device) and/or a more extensive equipment to accommodate a broader array of patient populations (e.g., bariatric). However, wherein such equipment is available within a freestanding facility or the use of such equipment is not essential to achieve the therapeutic goals, the medical necessity for a HOPD-based therapy is not established and delivering care in the freestanding facility would be appropriate.

Collaboration is another form of specialized care that is sometimes required to achieve the highest quality of care for a patient. This includes collaboration between therapy disciplines as well as collaboration between therapists and other providers. For instance, co-treatment of a traumatic brain injured patient by an occupational therapist and a speech therapist might be warranted to facilitate independence with self-care activities in the context of cognitive deficits. Additionally, that same patient's care might be more effective if his physical therapist is able to collaborate on-site with the physician who is medically managing his spasticity. Therefore, when such direct collaboration is needed and available only within the HOPD, the HOPD setting would be considered the most appropriate site.

Lastly, the primary principle guiding the site of care is ensuring the safety of the patient. Given the breadth of conditions and patients treated in outpatient therapy clinics, there is a broad range of medical needs, complexity and risk. Risk for adverse events occurring during therapy can be due to the condition being treated (as in cardiac rehab), a related clinical feature (e.g., labile blood pressures associated with a spinal cord injury) or an unrelated co-morbidity (e.g., angina in a knee replacement patient). In such situations, the potential need for proximal access to higher level care may warrant that therapy be rendered in a HOPD.

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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ICD-10 Diagnosis

Refer to the ICD-10 CM manual

History

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